General

Guideline Title

Guideline for selection and use of packaging systems for sterilization.

Bibliographic Source(s)

Spry C, Conner R. Guideline for selection and use of packaging systems for sterilization. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2013 Sep. p. 651-64. [56 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Note from the Association of periOperative Nurses (AORN): These recommended practices provide guidance to perioperative personnel for evaluating, selecting, and using packaging systems and for packaging the items to be sterilized and subsequently used in the perioperative setting. Packaging systems should permit sterilization of the contents within the package, protect the integrity of the sterilized contents, prevent contamination of the contents until the package is opened for use, and permit the aseptic delivery of the contents to the sterile field. Packaging systems include woven fabrics, non-woven materials, paper-plastic pouches, Tyvek®-plastic pouches, plastic-plastic pouches, and containment devices (e.g., sterilization containers, instrument cases, cassettes, organizing trays) composed of a variety of materials. These recommended practices do not include recommendations for cleaning contaminated instruments, loading a sterilizer, or sterilization.

I. Packaging systems and packaging materials should be evaluated before purchase and use (American National Standards Institute/Association for the Advancement of Medical Instrumentation [ANSI/AAMI], 2012).
II. Packaging systems should be compatible with the specific sterilization method for which they will be used.
III. Packaging materials should be processed and stored in a way that maintains the qualities required for sterilization.
IV. Items to be sterilized should be packaged in a manner that facilitates sterilization and provides for an aseptic presentation of the package contents. Packaging should be used according to the packaging manufacturer's and sterilizer manufacturer's written instructions for use (IFU).
V. Chemical indicators specific to the sterilization method selected should be used with each package (see the National Guideline Clearinghouse [NGC] summary of the AORN guideline Recommended practices for sterilization).
VI. Reusable woven packaging materials should be inspected and monitored throughout the life of the product.
VII. Peel pouches (i.e., paper-plastic, Tyvek, Mylar) should be used according to manufacturers' written IFU (ANSI/AAMI, 2012).
VIII. A rigid sterilization container should be used, cleaned, inspected, repaired, and maintained according to the manufacturer's written IFU.

IX. Packages to be sterilized should be labeled.
X. Perioperative team members with responsibilities for selection and/or use of packaging systems should receive initial and ongoing education and competency verification on their understanding of selection and use of packaging systems.
XI. Policies and procedures for selection and use of packaging systems should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting in which they are used.
XII. Perioperative personnel should participate in a variety of quality assurance and performance improvement activities that are consistent with the health care organization's plan to improve understanding of and compliance with the principles and processes of selection and use of packaging systems.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any condition requiring the use of surgical and other invasive procedures

Guideline Category

Prevention

Clinical Specialty

Nursing

Preventive Medicine

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Guideline Objective(s)

To provide guidance to perioperative personnel for evaluating, selecting, and using packaging systems and for packaging the items to be sterilized and subsequently used in the perioperative setting

Target Population

Patients undergoing surgical and other invasive procedures

Interventions and Practices Considered

1. Evaluation of packaging systems and packaging materials prior to purchase and use

2. Compatibility of packaging systems with specific sterilization methods
3. Processing and storage of packaging materials to maintain the qualities required for sterilization
4. Packaging of items to be sterilized in a manner that facilitates sterilization and provides for an aseptic presentation of the package contents
5. Packaging according to the packaging manufacturer's and sterilizer manufacturer's written instructions for use
6. Use of chemical indicators specific to the sterilization method selected with each package
7. Use of peel pouches (i.e., paper-plastic, Tyvek, Mylar) according to manufacturers' written instructions
8. Inspection and monitoring of reusable woven packaging materials
9. Cleaning, inspection, use and repair of rigid sterilization containers according to the manufacturer's written instructions
10. Labeling of packages to be sterilized
11. Initial and ongoing education and competency verification of preoperative team members on their understanding of selection and use of packaging systems
12. Development and periodic review of policies and procedures for selection and use of packaging systems
13. Participation of perioperative personnel in a variety of quality assurance and performance improvement activities

Major Outcomes Considered

- Processes to evaluate material quality after each use
- Patient safety
- Quality assessment
- Performance activities

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence Review

A medical librarian conducted a systematic literature search of the databases MEDLINE®, CINAHL®, Scopus®, and Cochrane Database of Systematic Reviews for meta-analyses, randomized and non-randomized trials and studies, systematic and non-systematic reviews, and opinion documents and letters.

Search terms included: surgical equipment, surgical instruments, dental instruments, organizing tray, instrument set, loaner instrument, medical packaging, product packaging, device packaging, product labeling, packaging material, sterilization container, rigid container, instrument case, instrument cassette, packaging system, reusable pack, pouch, heat sealer, sequential wrapping, plastics, textiles, fabrics, Mylar, Tyvek, Kraft, olefin, paper, polypropylene, polypropene, barrier integrity, barrier system, barrier properties, sterility maintenance cover, sterilization, flash sterilization, immediate use sterilization, infection control, microbial colony count, cross infection, equipment contamination, humidity, steam, condensation, equipment reuse, single-use, event-related, time-related, time-dependent, event-dependent, outdating, monitoring, quality control, materials testing, indicators and reagents, package integrity, equipment failure, safety management, hospital central supply, sterile processing, and hospital purchasing.

The lead author and the medical librarian identified and obtained relevant guidelines from government agencies, other professional organizations, and standards-setting bodies. The lead author assessed additional professional literature, including some that was cited in other articles provided to the author. The initial search was confined to the years 2005 to 2012 and limited to English-language articles. The time restriction was not applied in subsequent searches. The librarian also established continuing alerts on the topics included in this recommended practices document and provided relevant results to the lead author. The majority of research regarding packaging was related to shelf life and was conducted more than 10 years ago when facilities were transitioning from time-related shelf life to event-related shelf life. Articles addressing other aspects of packaging were quite limited. It is evident from the literature search that there is a need for additional research on all aspects of packaging for sterilization.

Number of Source Documents

77 articles met the inclusion criteria and were included in the review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

I: Randomized controlled trial (RCT) or experimental study, systematic review of all RCTs

II: Quasi-experimental study, systematic review of quasi-experimental studies or combination of quasi-experimental and RCTs

III: Non-experimental studies, qualitative studies, systematic review of non-experimental studies, combination of non-experimental, quasi-experimental, and RCTs, or any or all studies are qualitative

IV: Clinical practice guidelines, position or consensus statements

V: Literature review, expert opinion, case Report, community standard, clinician experience, consumer experience, organizational experience (quality improvement, financial)

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Articles identified by the search were provided to a doctorally prepared evidence appraiser and to the lead author for evaluation. Articles were critically appraised using the Johns Hopkins Evidence-Based Practice Model and the Research or Non-Research Evidence-Appraisal Tools as appropriate. The articles were independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score as agreed upon by the researcher and the lead author.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The collective evidence supporting each intervention within a specific recommendation was summarized and used to rate the strength of the evidence using the Association of periOperative Registered Nurses (AORN) Evidence Rating Model. Factors considered in review of the collective evidence were the quality of research, quantity of similar studies on a given topic, and consistency of results supporting a recommendation.

Rating Scheme for the Strength of the Recommendations

1: Strong Evidence: Interventions or activities for which effectiveness has been demonstrated by strong evidence from rigorously-designed studies, meta-analyses, or systematic reviews, rigorously-developed clinical practice guidelines, or regulatory requirements.

- Evidence from a meta-analysis or systematic review of research studies that incorporated evidence appraisal and synthesis of the evidence in the analysis.
- Supportive evidence from a single well-conducted randomized controlled trial.

- Guidelines that are developed by a panel of experts, that derive from an explicit literature search methodology, and include evidence appraisal and synthesis of the evidence.

1: Regulatory Requirement: Federal law or regulation.

2: Moderate Evidence: Interventions or activities for which the evidence is less well established than for those listed under "Strong Evidence."

- Supportive evidence from a well-conducted research study.
- Guidelines developed by a panel of experts which are primarily based on the evidence but not supported by evidence appraisal and synthesis of the evidence.
- Non-research evidence with consistent results and fairly definitive conclusions.

3: Limited Evidence: Interventions or activities for which there is currently insufficient evidence or evidence of inadequate quality.

- Supportive evidence from a poorly conducted research study.
- Evidence from non-experimental studies with high potential for bias.
- Guidelines developed largely by consensus or expert opinion.
- Non-research evidence with insufficient evidence or inconsistent results.
- Conflicting evidence, but where the preponderance of the evidence supports the recommendation.

4: Benefits Balanced With Harms: Selected interventions or activities for which the Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board (RPAB) is of the opinion that the desirable effects of following this recommendation outweigh the harms.

5: No Evidence: Interventions or activities for which no supportive evidence was found during the literature search completed for the recommendation.

- Consensus opinion

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Recommended Practices for Selection and Use of Packaging Systems for Sterilization have been approved by the Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board. They were presented as proposed recommendations for comments by members and others. They are effective November 15, 2013.

Evidence Supporting the Recommendations

References Supporting the Recommendations

ANSI/AAMI ST79:2010 & A1:2010, & A2:2011,& A3:2012: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Arlington (VA): Association for the Advancement of Medical Instrumentation; 2012.

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified for selected recommendations (see the "Major Recommendations" field). See the full guideline document for systematic review and discussion of evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate practices for selection and use of packaging systems for sterilization to enable the prevention of the spread of potentially pathogenic microorganisms and reduction of the risk of surgical site infection

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- These recommended practices represent the Association's official position on questions regarding optimal perioperative nursing practice.
- No attempt has been made to gain consensus among users, manufacturers, and consumers of any material or product.
- Compliance with the Association of periOperative Registered Nurses (AORN) recommended practices is voluntary.
- AORN's recommended practices are intended as achievable and represent what is believed to be an optimal level of patient care within surgical and invasive procedure settings.
- Although they are considered to represent the optimal level of practice, variations in practice settings and clinical situations may limit the degree to which each recommendation can be implemented.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Sep

Guideline Developer(s)

Association of periOperative Registered Nurses - Professional Association

Source(s) of Funding

Association of periOperative Registered Nurses (AORN)

Guideline Committee

Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board

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Financial Disclosures/Conflicts of Interest

No financial relationships relevant to the content of this guideline have been disclosed by the authors, planners, peer reviewers, or staff.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available to subscribers from the Association of periOperative Nurses Web (AORN) site .

Print copies: Available for purchase from the AORN Web site .

Availability of Companion Documents

The following is available:

- WB-packaging: not always so simple. Continuing education activity. Available from the Association of periOperative Nurses Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 17, 2014. The information was verified by the guideline developer on May 7, 2014.

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